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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,885	06/22/2001	Hirokazu Matsumoto	55999(46342)	7940
21874	7590	12/30/2004	EXAMINER	
EDWARDS & ANGELL, LLP			BASI, NIRMAL SINGH	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1646	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/868,885

### Applicant(s)

MATSUMOTO ET AL.

### Examiner

Nirmal S. Basi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/8/04 has been entered.

2. Amendments filed 11/8/04 and 10/6/04 have been entered. Applicant has cancelled claims 1-12 and added new claims 13-16.

### **Claim Rejection, 35 U.S.C. 112, first paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of regulating oxytocin secretion as disclosed in base claim 13, by administering oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, or a salt thereof, for G protein-coupled receptors phGR3, does not

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reasonably provide enablement for other oxytocin secretion regulators. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The critical feature required for activity of claimed ligand peptide is contained in the PrRP polypeptide fragments encompassed by SEQ ID NO:3, SEQ ID NO:18, SEQ ID NO:32 and SEQ ID NO:44. There is no disclosure of other compounds, which contain the critical feature of the invention, which can be isolated or produced to function as claimed. The disclosure does not teach how to isolate, make and purify ligands other than those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, which interact with G protein-coupled receptors phGR3 and have oxytocin secretion regulator functions, without undue experimentation. SEQ ID NO:44 is a generic sequence of a polypeptide, which encompasses mutations that retain functionality of G-protein-coupled, phGP3, interaction. Apart from the variable regions contained in SEQ ID NO:44, which are represented by SEQ ID NOs: 3, 18 and 32, there is no disclosure of other amino acids contained in SEQ ID NO:44, which can be changed or deleted to produce functional ligand peptide that retains functionality for G-protein-coupled, phGP3, interaction. The polypeptide disclosed in SEQ ID NO:44 contains 5 amino acids, represented as Xaa in the sequence listing, which can be changed to produce a functional polypeptide capable of being a functional oxytocin secretion regulator. It is suggested that the claim be limited to specific mutations disclosed by Xaa in SEQ ID NO:44 to overcome the rejection. The

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scope of the claims is limited for the reason given above and the previous Office Action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Normal S. Basi  
Art Unit 1646  
December 24, 2004

*Michael D. Pak*  
MICHAEL PAK  
PRIMARY EXAMINER